



MAR 20 2008

510(k) Summary Statement

Submitter: Vascular Insights, LLC
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Date Prepared: February 13, 2008
510(k) Number: K071468
Trade Name: ClariVein™ Infusion Catheter
Common Name: Infusion Catheter
Classification Name: Continuous Flush Catheter, 21 CFR 870.1210, Product Code KRA
Predicate Device(s): Trellis Infusion System (K013635)
Slip-Cath (K882796)

Device Description:

The ClariVein™ Infusion Catheter (ClariVein™-IC) is an infusion catheter system designed to introduce physician-specified medicaments into the peripheral vasculature. Infusion is through an opening at the distal end of the catheter and fluid delivery is enhanced by the use of a rotating dispersion wire to mix and disperse the infused fluid in the blood stream and on the vessel wall. The dispersion wire, connected to an interface cartridge for proximal connection to the motorized handle, extends through the catheter lumen. Prior to drug infusion the catheter sheath is inserted into the vasculature and once the catheter tip is positioned at the treatment site, the catheter sheath is retracted to expose the dispersion wire tip. Wire rotation is controlled by a 9V DC motorized Handle Unit. The Handle Unit also provides a grip and syringe holder to facilitate physician-controlled infusion.

Intended Use:

The ClariVein™-IC is intended for the infusion of physician-specified agents in the peripheral vasculature.

Technology:

The ClariVein™-IC is an infusion catheter system designed to introduce physician-specified medicaments into the peripheral vasculature. Infusion is through an opening at the distal end of the Catheter and fluid delivery is enhanced by the use of a rotating dispersion wire to mix and disperse the infused fluid in the blood stream and on the vessel wall. Dispersion wire rotation is controlled by a 9V DC motorized Handle Unit, which also provides a grip and syringe holder to facilitate physician-controlled infusion. The Handle contains a speed control adjustment knob for physician-selection speed of approximately 2,000 (low), 2,500 (medium), 3,000 (medium-high), and 3,500 (high) RPM. An interlock prevents the Motor Drive Unit (and dispersion wire rotation) from being activated if the Cartridge Unit (plus catheter) is out of position. A green LED light illuminates on the Handle Unit when the Motor Drive Unit is active (and dispersion wire is rotating). The wire dispersion tip has five different configurations to be chosen by the physician. The device is single-use and disposable. All patient-contact materials in ClariVein™-IC components are suitable for medical use and are commonly used in currently marketed infusion catheters.

ClariVein™-IC is substantially equivalent to the Trellis Infusion System (K013635) and the Slip-Cath Infusion Catheter (K882796). All three devices are intended to be used for infusion of physician-specified fluids into the peripheral vasculature. Similar to the Trellis, ClariVein™-IC, contains a sheathed dispersion wire that disperses the infused fluid and is operated via a hand-held, battery-powered motor. Similar to the Slip-Cath Infusion Catheter, ClariVein™-IC is a single lumen catheter with a diameter of approximately 3 Fr. All three catheters are disposable and are for single use.

Non-clinical Performance Testing:

Prior to marketing, ClariVein™-IC will be tested in accordance with ISO 10555-1, "Sterile, Single-Use Intravascular Catheters – Part 1: General Requirements." Additional testing (i.e., Dispersion Wire Tip Fatigue, Dispersion Wire Tip Tensile Test, System Simulated Procedure, and Wire Drive System Mechanical Strength) has already been conducted and shown that ClariVein™-IC performs adequately without failure.

Conclusion:

ClariVein™-IC is safe, performs adequately, and is substantially equivalent to identified predicate devices, i.e., the Trellis Infusion System (K013635) and the Slip-Cath Infusion Catheter (K882796).



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 20 2008

Vascular Insights, Inc.
c/o Mr. John P. Marano
395 Boston post Road
Madison, CT 06443

Re: K071468
Trade/Device Name: ClariVein Infusion Catheter
Regulation Number: 21 CFR 870.1210
Regulation Name: Continuous Flush Catheter
Regulatory Class: Class II (two)
Product Code: KRA
Dated: February 13, 2008
Received: February 13, 2008

Dear Mr. Marano:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Bram Zuckermann
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K071468

Device Name: ClariVein™ Infusion Catheter

Indications For Use: The ClariVein™ Infusion Catheter is intended for the infusion of physician-specified agents in the peripheral vasculature.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of Cardiovascular Devices

510(k) Number K071468

Page 1 of 1